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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,698	12/18/2001	Zishan Haroon	180/122/2	7501
25297	7590	01/29/2004	EXAMINER	
JENKINS & WILSON, PA 3100 TOWER BLVD SUITE 1400 DURHAM, NC 27707			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/025,698	HAROON ET AL.	
	Examiner	Art Unit	
	B. Dell Chism	1654	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's election without traverse of the restriction in the Office Action filed 15 September 2003 is acknowledged. The cancellation of non-elected claims 8-23 is also acknowledged.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-7 and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its

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face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (*In re Marzocchi*, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Colianni*, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986), and are summarized in *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

*The nature of the invention:* The claims invention is drawn to an agent comprising the peptide sequence of SEQ ID NO: 1 and a metal ion-chelator (MC) complex.

*The state of the prior art and the predictability or lack thereof in the art:* Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). As indicated in the specification at page 37 lines 1-4, the art acknowledges the use of the MC complex, Gd-DTPA, however, the art does not address the use of an MC used generally and/or basically with a peptide sequence of SEQ ID NO: 1 nor does the art teach the predictability of such an association for use as a contrast enhancement agent, whereby there is no predictability regarding the use of any MC with the claimed sequence regarding stereo-hindrance.

*The amount of direction or guidance present and the presence or absence of working examples:* Given the lack of teachings in the art regarding the making of a contrast enhancement agent comprising the peptide sequence of SEQ ID NO: 1 and a metal ion-chelator (MC) complex, detailed guidance is required in the specification to enable one of skill in the art to be able to make the claimed agents. This guidance is absent. The specification contains only a vague prophetic list of how one could make the claimed agents; however, there are no specific examples or adequate guidance for the making of the claimed agents. There are no demonstrations as how to select an adequate MC for a given peptide sequence comprising SEQ ID NO: 1 that would lead one of ordinary skill in the art away from undue experimentation regarding possible stereo-hindrances since it is not disclosed as to how the various MC's would be associated with the given sequence of SEQ ID NO: 1, i.e., is there an ionic association or a covalent association, or through which amino acid residue is the MC associating. The disclosure fails to establish that any amino acid would work at the X residue position with just any of the various MC's possible. The disclosure does not demonstrate which amino acid residue in SEQ ID NO: 1 would interact with the MC and would the association be affected by any of the many amino acids that could be at the X residue position.

*The breadth of the claims and the quantity of experimentation needed:* Given the lack of teachings regarding predictability in the art for a contrast enhancement agent comprising the peptide sequence of SEQ ID NO: 1 and a metal ion-chelator (MC) complex, and in the absence of sufficient guidance in applicant's disclosure to overcome the lack of teachings of predictability in the art, it would require undue experimentation by one of skill in the art to be able to use the claimed invention.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-7 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 24 are indefinite wherein it is unclear if "X" can be any natural amino acid or can be any natural and unnatural amino acid. Furthermore, it is unclear if "X" can be an amino acid, at least one paramagnetic metal ion and at least one chelator, or if "X" can only be an amino acid. The wording of the claims is indefinite and should be amended to clearly indicate that the agent comprises SEQ ID NO: 1, at least one paramagnetic metal ion and at least one chelator, and that "X" of SEQ ID NO: 1 can be any natural amino acid.

Claims 2-7 and 25 are rejected for depending from rejected claims.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Storey *et al.* (WO 99/60018). At pages 16-17, Storey *et al.* teaches peptides comprising sequences that read on the present SEQ ID NO: 1, wherein the peptides are to be associated with a MC that comprises: a) the presently claimed paramagnetic metal ions (see page 7 lines 5-26), and b) the presently claimed chelating compounds (see page 7 lines 27-30 and page 8 lines 1-30).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

***Conclusion***


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
21 January 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER